

**IN THE UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION**

PAMELA BUTLER,	)
	)
	)
Plaintiffs,	)
	)
vs.	) Case No. 4:18-cv-01701-AGF
	)
MALLINCKRODT LLC, et al.,	) Lead Case
	)
Defendants.	)

**PLAINTIFFS' ADDITIONAL STATEMENT OF FACTS:**

**FACTS RELATING TO COTTER'S CONDUCT**

1. Between 1969 and 1973, Cotter possessed and managed the radioactive waste at Latty Avenue. Mem. And Ord., p. 2.
2. In November 1970, an inspection of Latty Avenue was conducted. Ex. A Ryckman, Edgerley, Tomlinson and Associates, August 11, 1970, Site Visit Report, Cotter Corporation, Pg. 3).
3. As part of that inspection, health physics surveys performed by the licensee's consultant include stream samples, fallout tray samples, radiation level surveys at the fence line, and air sampling of work areas. *Id.*, p. 7.
4. The inspector concluded that Cotter Corporation was in noncompliance with 10 CFR 20.201(b) as the air sample survey it conducted were totally inadequate to determine concentrations of radioactive materials to which persons are exposed to pursuant to 10 CFR 20. *Id.*, p. 8.

5. In April of 1974, the AEC conducted three routine inspections of Cotter Corporation's Hazelwood, Missouri facility. (ECF No. 120-3, Pg. 74-79, US AEC May 17, 1974 Letter and Report. Pg. 3).

6. During that inspection it was determined that Cotter Corporation transferred and disposed of approximately 9700 tons of leached barium sulfate which contained approximately seven (7) tons of natural uranium to an unlicensed land fill in Bridgeton, Missouri. *Id.*, p. 3.

7. The AEC considered Cotter Corporation's transfer and disposal of licensed material to an unlicensed entity a clear violation of 10 CFR 20.301. *Id.*, p. 3.

#### **FACTS RELATED TO DR. WELLS' OPINIONS**

8. It is possible to calculate annual average concentrations from Dr. Wells' quarterly numbers. ECF No. 54-1, p. 24.

9. Annual average concentrations calculated from Dr. Wells' quarterly numbers show that for 1968, 1970, and 1971, the annual average for thorium-230 exceeds 0.08 pCi/m<sup>3</sup>. Wells Rep., p. 29, table 3(b), ECF No. 48-1.

10. Dr. Wells calculates the concentrations of thorium off-site for three quarters in a row—the third and fourth quarter of 1970, and the first quarter of 1971. Wells Rep., p. 29, table 3(b), ECF No. 48-1.

11. These quarterly calculations show that annual averages (calculated as the average of four quarterly estimates for each calendar year) still exceed regulatory limits. *Id.*

12. For example, he calculates the concentration of thorium for the third and fourth quarters of 1970 at 0.46 and 0.75 pCi/m<sup>3</sup>, respectively. *Id.*

13. Even if there were no emissions the rest of the year (there still would have been emissions of windblown dust from the Latty Avenue waste piles, so this is an extremely

conservative assumption), the annual average from all four quarters would be  $(0.46 + 0.75 + 0 + 0)/4 = 0.30 \text{ pCi/m}^3$ .

14. 0.30 pCi/m<sup>3</sup>, as an annual average, is higher than an annual average of 0.08 pCi/m<sup>3</sup>.

*Id.*

15. Similarly, for 1968, Dr. Wells calculated emissions for the 2nd, 3rd and 4th quarters. If emissions for the 1st quarter of 1968 were zero, the annual average would be  $(1.4 + 1.4 + .41 + 0)/4 = 0.80 \text{ pCi/m}^3$ . *Id.*

16. 0.80 pCi/m<sup>3</sup>, as an annual average, is ten times higher than an annual average of 0.08 pCi/m<sup>3</sup>. *Id.*

17. Even for 1971, for which Dr. Wells provides only one quarterly emissions estimate, the annual average still exceeded the regulatory limit of 0.08 pCi/m<sup>3</sup> for thorium:  $(0.41 + 0 + 0 + 0)/4 = 0.10 \text{ pCi/m}^3$ . *Id.*

#### **FACTS RELATED TO THE URANIUM MILL TAILINGS ACT:**

18. One of the documents reviewed and relied on by Defendants' experts is "USACE/SAIC 2005 Record of Decision for the North St. Louis County Sites St. Louis, Missouri." McClurg, ECF No. 711-6, p. 93.

19. This is a report by the U.S. Army Corps of Engineers, published on September 2, 2005 (Ex. J).

20. The report gives the history of the radioactive waste at issue in this case, including that "Mallinckrodt Chemical Works processed uranium feed material for the production of uranium metal from 1942 to 1957 under contracts with the MED/AEC." *Id.* at 2-3.

21. The report described how this waste was produced during the extraction of uranium from ore:

This work was performed at the Mallinckrodt Plant, on property known today as the SLDS. The original feed material used at SLDS was uranium black oxide that was extracted from uranium ore. Because of pre-processing, this black oxide was relatively free of radium and radium daughter products. In 1944, Belgian Congo Shinkolobwe ore containing high percentages of uranium (greater than 30% by weight) were processed. Processing activities at SLDS also included other ores with much lower concentrations of uranium in the ore. These less concentrated ores resulted in generation of larger quantities of byproduct waste with correspondingly lower activity concentrations (particularly with respect to daughter products).” *Id.*

22. This waste is what was stored at SLAPS, and later, some of it, at Latty Avenue:

In 1946, the AEC acquired the 21.7-acre tract of land (now known as the SLAPS) in what was then an undeveloped area of north St. Louis County to store process byproducts and scrap from uranium processing at the Mallinckrodt Plant. The following byproducts and scrap were transported mainly from the SLDS to the SLAPS for storage:

- Radium-bearing residues, referred to as “K-65” residues;
- AM-7 Pitchblende raffinate cake;
- AM-10 or Colorado raffinate cake;
- AJ-4 Barium Sulfate Cake (unleached) and AJ-4 Barium Cake (leached);
- C-liner slag that was created during metal forming operations;
- C-701 U scalping of magnesium fluoride, Japanese precipitates, and Vitro residues from the Vitro Corporation’s facility in Canonsburg, PA; and
- Empty drums, contaminated steel and alloy scrap, and building debris.

*Id.*

23. It confirms “Uranium processing residues and wastes resulting from the ore-processing activities at SLDS were stored at SLAPS beginning in 1946.” *Id.*

24. Hence, the radioactive materials in this case are wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content. *Id.*

25. In 1978, Congress passed the Uranium Mill Tailings Control Act (UMTCA). Ex. B, Public Law 95-604, Nov. 8, 1978, at 92 STAT. 3022.

26. In the UMTCA, Congress for the first time expanded the definition of “byproduct material” to include “wastes produced by the extraction or concentration of uranium or thorium for any ore processed primarily for its source material content.” *Id.*, at 92 STAT. 3033.

27. In 1979, the Nuclear Regulatory Commission (NRC) amended the licensing requirements found in 10 C.F.R. Part 40 to cover wastes produced by the extraction of or processing of uranium. Specifically, it added “byproduct material” to the definitions found under 10 C.F.R. § 40.4 as meaning “tailings or wastes produced by the extraction or concentration of uranium.” Ex. C, 44 F.R. 50013, August 24, 1979; *See also*, Ex. D, 47 F.R. 57446-01, December 27, 1982 (“uranium and thorium tailings as defined in Section 11e(2) of the Atomic Energy Act of 1954, as amended, are not subject to the requirements of Part 61, but are disposed of according to requirements in 10 CFR Part 40”).

#### **FACTS RELATING TO DEFENDANTS’ RADIOACTIVE WASTE CAUSING CANCER IN THE COMMUNITY**

28. Dr. Hu reviewed and relied on documents and reports beyond Dr. Clark’s report, including ATSDR. Evaluation of Community Exposures Related to Coldwater Creek St Louis Airport/Hazelwood Interim Storage Site (HISS) ZFutura Coatings NPL Site, North St Louis County, Missouri. EPA Facility ID MOD980633176. June 18, 2018 Draft Report. Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services (“ATSDR Draft Report”). Dr. Hu’s Reports, ECF Nos. 52-1, 52-2, 52-3, and 53-4; pp 2-3.

29. The ATSDR Draft Report evaluated exposures to people who played or lived near Coldwater Creek in North St. Louis County, Missouri, which in turn, was the site of the release of radiological waste storage sites near the St. Louis Airport in the past. (Ex. E, ATSDR, Evaluation of Community Exposures Related to Coldwater Creek St Louis Airport/Hazelwood Interim Storage Site (HISS)/Futura Coatings NPL Site, North St Louis County, Missouri. EPA Facility ID MOD980633176”).

30. According to the ATSDR Draft Report People playing or living downstream of the source areas near Coldwater Creek (now or in the past) may have been exposed to contaminants

that washed down the creek through both residential exposures as well as recreational exposures. *Id.*, Pg. 10; the same is found in the ATSDR's 2019 Final Report, (ECF 50-3, 2019 ATSDR Final Report, Evaluation of Community Exposures Related to Coldwater Creek, Pg. 12 (hereinafter, "ATSDR 2019 Final").

31. The radiologic and chemical contaminants associated with the historical source areas traveled downstream with creek sediments. (Ex. E, ATSDR 2018 Draft, Pg. 10; ECF 50-3, ATSDR 2019 Final, Pg. 12).

32. People could have been exposed by contacting sediment, water (with suspended sediment in it), or floodplain soils (contaminated with sediment during flood events). *Id.*

33. They could take contaminants into their bodies by accidentally swallowing small amounts of sediment, water, or soil. *Id.*

34. They could also breathe contaminants if their activities suspend enough dust from dry, contaminated soil. (Ex. E, ATSDR 2018 Draft, Pg. 10-11; ECF 50-3, ATSDR 2019 Final, Pg. 12-13).

35. If the contaminants are radioactive, people may receive an external dose of radiation just from being near the contamination. (Ex. E, ATSDR 2018 Draft, Pg. 11; ECF 50-3, ATSDR 2019 Final, Pg. 12).

36. In ATSDR's review of the available data collected from recreational and residential stretches of Coldwater Creek as it pertained to potential community exposures, the ATSDR noted that testing demonstrated that thorium-230 (Th-230) was present in soil and sediment at levels consistently above typical background levels (1 to 3 picocuries per gram (pCi/g) for soil and sediment). (Ex. E, ATSDR 2018 Draft, Pg. 14; ECF 50-3, ATSDR 2019 Final, Pg. 15).

37. It was also detected frequently above FUSRAP's remedial goal for Th-230 in soil (14–15 pCi/g). *Id.*

38. ATSDR modeled exposure point concentrations for soil, sediment, and surface water for past historical and recent exposures. The end results are summarized in Table 1:

Table 1 summarizes the selected past and recent exposure point concentrations for soil, sediment, and surface water used in this evaluation.

**Table 1. Exposure point concentrations for soil, sediment, and surface water at Coldwater Creek**

Contaminant	Past Exposure Point Concentration		Recent Exposure Point Concentration			
	Soil (pCi/g)*	Sediment (pCi/g)*	Surface water (pCi/L)†	Soil (pCi/g)*	Sediment (pCi/g)*	Surface water (pCi/L)†
Thorium-230	54.5	105.4	4.65	27.3	7.9	4.65
Radium-226	2.5	4.8	0.88	1.9	1.8	0.88
Uranium-238	2.3	4.5	5.05	1.8	1.0	5.05

Used past exposure point concentrations to estimate exposures occurring from the 1960s to the 1990s.

Used recent exposure point concentrations to estimate potential exposures occurring since the 2000s.

pCi/g = picocuries per gram

pCi/L = picocuries per liter

\*See Appendix C for explanation of soil and sediment exposure point concentration selection.

†Background criteria for surface water [6]. No positively identified results for surface water in areas at or downstream of I-270 were higher than background criteria.

(Ex. E, ATSDR 2018 Draft, Pg. 18; ECF 50-3, ATSDR 2019 Final, Pg. 19).

39. The ATSDR's draft report determined that many residents were likely subject to radionuclide exposures to some degree through inhalation, ingestion and skin contact, and that the magnitude of the doses received, particularly in the past, were in addition to background levels to a significant degree for some residents. (Ex. E, ATSDR 2018 Draft, Pg. 11-14; ECF 50-3, ATSDR 2019 Final, Pg. 12-15).

40. According to the ATSDR's draft Report, testing demonstrated that Thorium-230 was present in soil and sediment at levels consistently above typical background levels (1-3 pCi/g). (Ex. E, ATSDR 2018 Draft, Pg. B-3; ECF 50-3, ATSDR 2019 Final, B-3).

41. According to the ATSDR's Draft Report, Thorium-230 was also detected frequently above FUSRAP's remedial goal for contamination in soil (14-15 pCi/g). *Id.*

42. The 2019 ATSDR Report sets the background for thorium in soil at 1-3 pCi/m<sup>3</sup> and then chronicles the thousands of measurements above this background level. *Id.*, Table B.1 at p. B-3.

43. Some of these measurements exceed background level by up to 30 times. *Id.*

44. The ATSDR Report even goes so far as to identify entire areas in and around the creek that are radioactive “hot spots” because of how far above background the soil and sediment samples are. *Id.*, at 18.

45. On April 30, 2019, the Agency for Toxic Substances and Disease Registry (ATSDR) published its Public Health Assessment of the community exposure related to Cold Water Creek (“ATSDR Final Report”). ECF No. 50-3.

46. The ATSDR Final Report contained the same statements from the Draft Report referred to above and concluded: “Radiological contamination in and around Coldwater Creek, prior to remediation activities, could have increased the risk of some types of cancer in people who played or lived there.” *Id.*, p. 6.

47. The ATSDR also concluded: “Other exposure pathways of concern to the community could have contributed to risk. ATSDR is unable to quantify that risk.” *Id.*, p. 8.

48. The ATSDR concluded: “Radiological contamination in and around Coldwater Creek, prior to remediation activities, could have increased the risk of some types of cancer in people who played or lived there.” *Id.*, p. 6.

49. The ATSDR also concluded: “Other exposure pathways of concern to the community could have contributed to risk. ATSDR is unable to quantify that risk.” *Id.*, p. 8.

50. But of the exposure pathways the ATSDR focused on, it was able to quantify the risk:

The process used by ATSDR is reasonable for the purposes of our public health assessment. ATSDR recognizes that EPA's 2011 lifetime attributable risk coefficients were designed to be used with absorbed dose in a given year and then integrated over the years of exposure and dose. For multiple years of intake this becomes very complicated, typically requiring specialized computer programs that cannot be easily explained to or replicated by members of the public. In contrast, ATSDR estimated the committed dose to age 70 for every year of intake separately, and applied that committed dose in the year the intake occurred. **This simplifies the calculations and allows clear presentation of the estimated dose and risk for each year an intake occurred.**

To test how ATSDR's method compared with integrative methods, we used the AcuteDose code to estimate absorbed organ-specific doses for each year to age 70 and applied the 2011 lifetime attributable risks to determine lifetime cancer risks resulting from 33 years of intake, using the assumptions developed for the Coldwater Creek evaluation [136]. **ATSDR's simplified method gives cumulative dose estimates and lifetime cancer risks generally comparable with the more complicated approach. We concluded that our methodology would be a reasonable approximation for estimating lifetime risks.** We recognize that this approach would not be used in a detailed dose reconstruction. We believe the improved accessibility of the calculations for the general public outweighs any inaccuracies introduced by our method.

*Id.*, F-11 (emphasis added)).

51. Dr. Hu also cites to and relies on a 2014 study by the Missouri Department of Health and Senior Services (DHSS). Ex. F, Yun S. Schmaltz CL, Gwanfogbe P, Homan S, Wilson J. Analysis of cancer incidence data in eight ZIP code areas around Coldwater Creek, 1996-201 1. Missouri Department of Health and Senior Services, September 2014. *See also* ECF No. 52-4, Hu Report as to Butler, p. 14.

52. Defendants' Experts, RAC, identified this same report as among the almost One Hundred Thousand (100,000) pages of documents they had time to review and rely on before preparing their reports in the *McClurg* cases. *McClurg*, ECF No. 711-6, p. 97.

53. In this report, the DHSS studies cancer rates in eighth zip codes along Cold Water Creek. Ex. F.

54. In this report, the DHSS concludes that in these zip codes “The number of female breast cancer cases was statistically significantly higher than expected, as was the number of colon, prostate, kidney and bladder cancers in the area.” *Id.*, p. 9.

55. The DHSS also concludes that “In the combined ZIP code area during 1996-2011, the number of incident cases of leukemia was statistically significantly higher.” *Id.*

56. The DHSS also concludes: “The number of incident cases of brain and other nervous system cancer among children age 17 or younger was significantly higher than expected in ZIP code 64043 during 1996-2011.” *Id.*

#### **FACTS RELATING TO DR. HU’S GENERAL CAUSATION OPINIONS**

57. Dr. Hu notes in his report that the specific radionuclides associated with Coldwater Creek (Uranium-238, Uranium-236, Thorium-230, Thorium-232, and Radium-226), the associated ionizing radiation (which raises the risk of cancer, as noted above) generally takes the form of alpha particles, beta particles, and, to some extent, gamma radiation, which are released during the decay process and that each one is carcinogenic (able to cause cancer). Dr. Hu Expert Report for Emery Walick, III, p. 7. ECF No. 52-5.

58. The International Agency for Research on Cancer considers all internalized radionuclides that emit either alpha particles or beta particles to be carcinogenic to humans. *Id.*, at 7-8.

59. The 2018 ATSDR draft report determined that many residents were likely subject to radionuclide exposures to some degree through inhalation, ingestion and skin contact and that the magnitude of the doses received, particularly in the past, likely exceeded background levels to a significant degree for some residents. *Id.*, at 8.

60. In its 2019 report, the ATSDR stated that, “most regulatory and advisory agencies assume every dose of radiation, no matter how small, incrementally increase the risk of developing

cancer.” ATSDR Public Health Assessment for Evaluation of Community Exposures Related to Coldwater Creek (2019), p. 21, ECF No. 50-3.

61. Dr. Hu opined that based on reports from the Biological Effects of Ionizing Radiation Committee (BEIR VII) and the USEPA, current evidence and research, the probability of developing cancer increases in a linear manner with incremental increases in radiation dose even at relatively low levels of exposure. Hu Dep., 134:19-135:13, ECF No. 52-5.

62. Dr. Hu has also offered the following testimony concerning the levels of radiation which can cause cancer:

As I stated in my reports, in the opinion of the most recent report of the Biological Effects of Ionizing Radiation Committee, that's the BEIR VII report and the USEPA, current evidence, including recent research, continues to favor the linear no-threshold model of carcinogenesis, i.e., the probability of developing cancers is presumed to increase in a linear manner with incremental increases in radiation dose even at relatively low levels of exposure.

ECF No. 52-5, 134:19-135:4

**Q:** What has changed in the intervening years that led you to believe that is no longer a hypothesis?

**A:** Well, there's been quite a bit of research done in the last 25 years since this book was published, and there's been studies that have looked at very large populations by pooling data, meta- analyses, *et cetera*, that still see a signal of cancer risk at very low doses of radiation, which has been interpreted as support for what is now termed the linear no-threshold model as opposed to a hypothesis.

ECF No. 70-19, 169:7-18.

**Q:** (By Mr. Watson) Outside of the regulatory community, is it accepted in the epi community?

**A:** I think there's some controversy here, but I think in general my colleagues in general are aligned with that theory.

**Q:** Can you say to a reasonable degree of medical certainty that the linear no threshold theory is appropriate for low dose radiation without an epi study?

**A:** Well, as far as I know, when the Biological Effects of Ionizing Radiation Committee considered the dose response relationship they were both looking at the epidemiologic literature as well as the experimental literature, so yeah, even discounting the epidemiology literature, I think there's -- there is substantial experimental literature supporting the linear no threshold model.

ECF No. 70-14, 114:18-115:9.

## **PAMELA BUTLER**

### **Pamela Butler's Exposure to Radionuclides**

63. Mrs. Butler was a resident of Hazelwood and Ferguson, Missouri from 1983 through 1993. (Ex. G, Pamela Butler Plaintiff Questionnaire, Pg. 3-4).

64. Mrs. Butler initially resided at 311 Avant Drive, in Hazelwood, Missouri (zip code area 63042), approximately 125 meters west of the Coldwater Creek, after moving to the area from Fort Wayne, Indiana. *Id.*

65. While living at the Avant Drive residence, Mrs. Butler would walk along the Coldwater Creek basin and was known to collect rocks from the creek basin. (Ex. G, Pamela Butler Plaintiff Questionnaire, Attachment to Pg. 9); ECF No. 52-5, Deposition of Pamela Butler, 39:6-24).

66. According to the ATSDR's Coldwater Creek Public Health Assessment, this location where Mrs. Butler would walk along the Creek basin is a "Hotspot" area. Exh. E, ATSDR 2018 Draft, Pg. 16, Fig. 5 (Quadrant E-L); ECF 50-3, ATSDR 2019 Final, Pg. 16, Fig. 5 (Quadrant E-L).

67. According to the ATSDR's Report, Sector E-left for past exposures were 13.7 pCi/g. (Ex. E, ATSDR 2018 Draft, Pg. C-6; ECF 50-3, ATSDR 2019 Final, Pg. C-6).

68. The ATSDR considers 3 pCi/g to represent a value statistically different than background. *Id.*

69. In 1985, the Butlers moved to 2 Frost Avenue, Ferguson, Missouri (zip code area 63135). (Ex. G, Pamela Butler Plaintiff Questionnaire, Pg. 3-4).

70. While living at the Frost Avenue site, Mrs. Butler would frequently meet her husband in the field at the northwest corner of Eva Avenue and James S. McDonnel Boulevard (the Ball Field Area north of SLAPS) to train/walk her dog and to have lunch together. (Ex. G, Pamela Butler Plaintiff Questionnaire, Attachment to Pg. 9; ECF No. 52-5, Deposition of Pamela Butler, 66:24-67:12;69:5-20; 72:10-15; ).

71. Soils from the Ballfields exceeded background levels of radiation for Radium-226, Thorium-230 and Uranium-236 which was discovered in 1998 during a walkover survey to define the extent of contamination of areas near Coldwater Creek. US Army Corp of Engineers, Second Five-Year Review Report for Formerly Utilized Sites Remedial Action Program (FUSRAP) St. Louis Sites (2010), VII-7, IV-36 (Ex. P).

72. The ATSDR stated that people who were exposed in the past at the ball fields could have higher exposures and be at a higher risk. (ECF 50-3, ATSDR Evaluation of Community Exposures Related to Coldwater Creek (2019), F-25).

73. The Butler's dog was frequently covered in dust and mud from playing in the ballfield and in the ditches adjacent to the ballfield. (ECF No. 52-5, Deposition of Pamela Butler, 95:23-97:3).

74. Mrs. Butler would have to clean the dog and would be in contact with the mud/dust. *Id.*

75. Dr. Hu noted that the mud and dust picked up from the dog at the ballfield was not considered in Dr. Clark's exposure estimate but opined that such contamination significantly

contributed to Mrs. Butler's exposures to radionuclides. (ECF No. 52-4, Dr. Howard Hu Expert Report for Pamela Butler (04/01/19), Pg. 4).

**Mrs. Butler's Diagnosis of Breast Cancer**

76. In June of 2016, Ms. Butler was found to have a 1 cm left breast mass on a routine mammogram; biopsy revealed invasive ductal carcinoma, Nottingham score of 5, T1cN1aM0, estrogen receptor positive, progesterone receptor positive, Her2Neu negative, unamplified, and an oncotype score of 15 (10% chance of distant recurrence). (ECF No. 52-4, Dr. Howard Hu Expert Report for Pamela Butler (04/01/19), Pg. 4).

**Dr. Hu's Expert Opinion ruled out other causes of her breast cancer**

77. Dr. Hu ruled-out that Ms. Butler's breast cancer was caused by alternative causes other than Defendants' radioactive waste, and the Court did not exclude these opinions, finding them sufficiently reliable to be admissible. Mem. and Ord. pp. 39-40; Hu. Butler Report, pp. 12-13, ECF No. 52-4; Hu Supplemental Butler Report, pp. 2-4, ECF No. 52-14.

**Dr. Hu's General Causation Opinions Regarding Defendants' Radioactive Waste and Ms. Butler's Breast Cancer.**

78. Dr. Hu opines that Defendants' radiation can cause Ms. Butler's breast cancer, and the Court did not exclude this opinion, finding it sufficiently reliable to be admissible. Mem. and Ord. pp. 37-38; Hu. Butler Report, ECF No. 52-4; Hu Supplemental Butler Report, ECF No. 52-14.

79. The International Agency for Research on Cancer (IARC) designated ionizing radiation (in the form of X radiation or gamma radiation) as a known risk factor for the development of breast cancer based on evidence in humans as well as strong mechanistic data and other considerations. (ECF No. 52-4, Dr. Howard Hu Expert Report for Pamela Butler (04/01/19), Pg. 10) (citing IARC. International Agency for Research on Cancer. IARC Monographs on the

Evaluation of Carcinogenic Risks to Humans. Volume 75: Ionizing Radiation, Part 1: X- and Gamma-Radiation, and Neutrons. Lyon, France: IARC, World Health Organization, 2000; Cogliano VJ, Baan R, Straif K, Grosse Y, Lauby-Secretan B, El Ghissassi F, Bouvard V, Benbrahim-Tallaa L, Guha N, Freeman C, Galichet L, Wild CP; Preventable exposures associated with human cancers. *J Natl Cancer Inst.* 2011 Dec 21;103(24):1827-39. doi: 10.1093/jnci/djr483. Epub 2011 Dec 12. Review. PubMed PMID: 22158127; PubMed Central PMCID: PMC3243677).

80. Radium sheds carcinogenic alpha-particles, and deposits in soft tissue, such as breast tissue, with the accompanying potential for radiation effects in these tissues. (ECF No. 52-4, Dr. Howard Hu Expert Report for Pamela Butler (04/01/19), Pg. 11)

81. Prospective epidemiologic studies found exposure to radium-224 resulted in an increase in the incidence of female breast cancer. (ECF No. 52-4, Dr. Howard Hu Expert Report for Pamela Butler (04/01/19), Pg. 11 (citing Nekolla EA, Kellerer AM, Kuse-Isingschulte M, Eder E, Spiess H. Malignancies in patients treated with high doses of radium-224. *Radiat Res.* 1999 Dec;152(6 Suppl):S3-7. PubMed PMID: 10564925).

82. Dr. Hu opines that exposure to radium-224 causes breast cancer as well as that such exposure during childhood poses a much greater risk for the induction of breast tumors than does exposure as an adult. (ECF No. 52-4, Dr. Howard Hu Expert Report for Pamela Butler (04/01/19), Pg. 11 (citing Nekolla EA, Kellerer AM, Kuse-Isingschulte M, Eder E, Spiess H. Malignancies in patients treated with high doses of radium-224. *Radiat Res.* 1999 Dec;152(6 Suppl):S3-7. PubMed PMID: 10564925; and Spiess H, Mays CW, Chmelevsky D. 1989. Malignancies in patients injected with 224Ra. *Br J Radioi* 21:7-11.

83. Dr. Hu concludes that exposure to radium is a known risk of causing breast cancer. (ECF No. 52-4, Dr. Howard Hu Expert Report for Pamela Butler (04/01/19), Pg. 11.

84. The ATSDR has specifically listed radium as a risk factor for breast cancer. (See <https://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=790&tid=154> (accessed March 11, 2019)).

85. The ATSDR draft report noted: "Past residential exposures at Coldwater Creek could have resulted in doses to the breast up to 320 mrem." (Ex. E).

86. In 2014, the Missouri Department of Health that concluded a statistically significant increase in breast cancer exists in area codes 63042 and 63134, where a significant amount of Ms. Butler's exposure occurred. ECF No. 52-4, at 13 (citing Yun S, Schmaltz CL, Gwanfogbe P, Homan S, Wilson J. Analysis of cancer incidence data in eight ZIP code areas around Coldwater Creek, 1996-2011. Missouri Department of Health and Senior Services, September 2014).

87. Ms. Butler's personal exposure history includes walking her dog from 1985-1993 to a field that straddles zip codes 63042 and 63134. Both of these zip codes are within the zone of exposure associated with an elevated risk of breast cancer in the Missouri study. (ECF No. 52-4, Dr. Howard Hu Expert Report for Pamela Butler (04/01/19), Pg. 13).

## **ANTHONY HINES**

### **Anthony Hine's Exposure to Radionuclides**

88. Mr. Hines was a resident of St. Louis, Missouri from his birth (November 1962) through 1973 and again from 1975 through 1983. (Ex. H, Anthony Hines Plaintiff Questionnaire, Pg. 2, 3 and Attachment to Pg. 3).

89. Mr. Hines resided at 221 Sadonia Street, which is located between the neighborhoods of Calverton Park and Berkeley in the 63135 zip code. (Ex. H, Anthony Hines Plaintiff Questionnaire, Attachment to Pg. 3).

90. His family residence at 221 Sadonia Street is approximately 1.4 miles east of the Hazelwood Interim Storage Site (HISS)/Futura Site, 1.6 miles east of the entrance to Coldwater

Creek (via Latty Avenue), and 1.65 miles north, northeast of the Saint Louis Airport Site (SLAPS).

*Id.*

91. As a child he would spend most days playing along the Coldwater Creek basin, in particular, in the area to the west of the HISS/Futura Site and north of the SLAPS site. (Ex. I, Deposition of Anthony Hines, 51:17-52:24; Ex. H, Anthony Hines Plaintiff Questionnaire, Pg. 9-10 and Attachment to Pg. 9).

92. Mr. Hines testified that he began going to the creek at the age of seven. (Ex. I, Deposition of Anthony Hines, Deposition of Anthony Hines, Pg. 68:12-16.

93. Anthony and his friends played in Coldwater Creek, fished in Coldwater Creek, caught and consumed crawdads from Coldwater Creek, rode their bikes in and around the Creek, and even tried to jump the creek on their bikes. (Ex. I, Deposition of Anthony Hines, 53:4-55:7; Ex. H, Anthony Hines Plaintiff Questionnaire, Pg. 9-10 and Attachment to Pg. 9).

94. From age 7 (1969) Mr. Hines lived at 221 Sadonia until they moved away briefly in 1974 at the age 12. (Ex. H, Anthony Hines Plaintiff Questionnaire, Pg. 2, 3 and Attachment to Pg. 3

95. Mr. Hines moved back to 221 Sadonia in 1977 and continued to live there until 1983 when he turned 21. *Id.*

96. He testified that he did not stop going to the creek until he turned 18 in 1980. (Ex. I, Deposition of Anthony Hines, Pg. 61:4-62:4).

97. Mr. Hines and his friends played in a treehouse at the end of Latty Avenue (adjacent to the HISS/Futura Site). (Ex. I, Deposition of Anthony Hines, Pg. 50:3-52:3; Ex. H, Anthony Hines Plaintiff Questionnaire, Pg. 9-10 and Attachment to Pg. 9).

98. In addition to playing along the Creek, Mr. Hines played in the Ball Field Area immediately north of the SLAPS site. (Ex. I, Deposition of Anthony Hines, Pg. 176:3-178:20; Ex. H, Anthony Hines Plaintiff Questionnaire, Pg. 9-10 and Attachment to Pg. 9).

99. Playing at the treehouse was a regular activity for Mr. Hines when he visited the creek. (Ex. I, Deposition of Anthony Hines, Pg.49:19-23).

100. Mr. Hines would play at either the creek or the clubhouse which was 50-100 ft from the creek. (Ex. I, Deposition of Anthony Hines, Pg. 51:20-52:5).

101. In summer, Mr. Hines would play at the creek frequently from sunup to sundown. (Ex. I, Deposition of Anthony Hines, Pg. 52:18-24; Pg. 54:18-21).

102. Mr. Hines testified that he continued to go to the clubhouse when he moved back to 221 Sadonia in 1976. (Ex. I, Deposition of Anthony Hines, Pg. 60:9-12).

103. Mr. Hines stated that he played year-round in and on the banks of the creek, even in the winter. (Ex. H, Anthony Hines Plaintiff Questionnaire, Pg. 9-10 and Attachment to Pg. 9).

104. According to the US Army Corp of Engineer's Record of Decision, this location where Mr. Hines would play at the end of Latty Avenue tested radium, thorium and uranium in excess of background levels of radiation. (Ex. J, US Army Corp of Engineers 2005 Record of Decision for the North St. Louis County Sites, Figure 2-9; Ex. K, USACE 2014 St. Louis Formerly Utilized Sites Remedial Action Program Activities, Pg. 2-3).

105. According to the ATSDR's Draft and Final Reports, Sector E-left for past exposures were 13.7 pCi/g. (Ex. E, ATSDR 2018 Draft, C-6; ECF 50-3, ATSDR 2019 Final, C-6)

106. The ATSDR considers 3 pCi/g to represent a value statistically different than background. *Id.*

107. The ATSDR stated that people who were exposed in the past at the ball fields could have higher exposures and be at a higher risk. (ECF 50-3, ATSDR Evaluation of Community Exposures Related to Coldwater Creek (2019), F-25).

**Mr. Hines's Diagnosis of mantle cell lymphoma**

108. In 2015 a biopsy of the lymph node in Mr. Hines' right axilla revealed mantle cell lymphoma. (ECF No. 52-1, Dr. Howard Hu Expert Report for Anthony Hines (04/01/19), Pg. 3).

109. A subsequent bone marrow biopsy showed normocellular bone marrow with diffuse involvement of the lymphoma. (ECF No. 52-1, Dr. Howard Hu Expert Report for Anthony Hines (04/01/19), Pg. 3).

110. Mr. Hines' final diagnosis was stage IV mantle cell lymphoma. (ECF No. 52-1, Dr. Howard Hu Expert Report for Anthony Hines (04/01/19), Pg. 3).

**Dr. Hu's Expert Opinion ruled out other causes of Mr. Hines' Mantle Cell Lymphoma**

111. Dr. Hu ruled-out that Mr. Hines' Mantel Cell Lymphoma was caused by alternative causes other than Defendants' radioactive waste, and the Court did not exclude these opinions, finding them sufficiently reliable to be admissible. Mem. and Ord. pp. 39-40; Hu. Hines Report, pp. 12-13, ECF No. 52-1; Hu Supplemental Hines Report, pp. 2-4, ECF No. 52-15.

**Dr. Hu's General Causation Opinions Regarding Defendants' Radioactive Waste and Mr. Hines' Mantel Cell Lymphoma.**

112. Mantle Cell Lymphoma is considered a relatively rare separate sub-type of non-Hodgkins lymphomas. (ECF No. 52-1, Dr. Howard Hu Expert Report for Anthony Hines (04/01/19), Pg. 7-8) (citing Wang Y, Ma S. Risk factors for etiology and prognosis of mantle cell lymphoma. Expert Rev Hematol. 2014 Apr;7(2):233-43. doi: 10.1586/17474086.2014.889561. Epub 2014 Feb 22. Review. PubMed PMID: 24559208; PubMed Central PMCID: PMC4465399. Smedby KE, Hjalgrim H. Epidemiology and etiology of mantle cell lymphoma and other non-

Hodgkin lymphoma subtypes. *Semin Cancer Biol.* 2011 Nov. 21(5):293-8. doi: 10.1016/j.semancer.2011.09.010. Epub 2011 Sep 18. Review. PubMed PMID: 21945518).

113. Epidemiologic cohort studies of cancer in populations specifically exposed to radiation exposure, NHL has generally been considered as a single outcome combining all NHL subtypes. (ECF No. 52-1, Dr. Howard Hu Expert Report for Anthony Hines (04/01/19), Pg. 8).

114. Dr. Hu opines that due to the literature on epidemiology and etiology of mantle cell lymphoma and other non-Hodgkin lymphoma subtypes, studies of radiation and non-Hodgkins lymphoma are relevant to Mantle Cell Lymphoma. (ECF No. 52-1, Dr. Howard Hu Expert Report for Anthony Hines (04/01/19), Pg. 8).

115. The International Agency for Research on Cancer (IARC) designated ionizing radiation (in the form of X radiation or gamma radiation) as a known risk factor for the development of NHL based on evidence in humans as well as strong mechanistic data and other considerations. (ECF No. 52-1, Dr. Howard Hu Expert Report for Anthony Hines (04/01/19), Pg. 7-8) (citing IARC. International Agency for Research on Cancer. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 75: Ionizing Radiation, Part 1: X- and Gamma-Radiation, and Neutrons. Lyon, France: IARC, World Health Organization, 2000;18 Cogliano VJ, Baan R, Straif K, Grosse Y, Lauby-Secretan B, El Ghissassi F, Bouvard V, Benbrahim-Tallaa L, Guha N, Freeman C, Galichet L, Wild CP. Preventable exposures associated with human cancers. *J Natl Cancer Inst.* 2011 Dec 21;103(24):1827-39. doi: 10.1093/jnci/djr483. Epub 2011 Dec 12. Review. PubMed PMID: 22158127; PubMed Central PMCID: PMC3243677).

116. Exposure to thorium sheds carcinogenic alpha-particles, and autopsy studies clearly show that lymph nodes are a major site of deposition for thorium in the human body. (ECF No. 52-1, Dr. Howard Hu Expert Report for Anthony Hines (04/01/19), Pg. 8) (citing Ishikawa Y,

Humphreys JA, Collier CG, Priest ND, Kato Y, Mori T, Machinami R. Revised organ partition of thorium-232 in thorotrust patients. *Radiat Res.* 1999 Dec;152(6 Suppl):S102-6. PubMed PMID: 10564947; Mausner LF. Inhalation exposures at a thorium refinery. *Health Phys.* 1982 Feb;42(2):231-6. PubMed PMID: 7068387).

117. Exposure to thorium has also been shown to induce fibrosis of the lymph nodes in humans. (ECF No. 52-1, Dr. Howard Hu Expert Report for Anthony Hines (04/01/19), Pg. 8) (citing Wegener K, Wesch H. Pathological changes of lymph nodes in thorotrust patients: pathoanatomical, autoradiographical, and quantitative investigations. *Environ Res.* 1979 Feb;18(1):245-55. PubMed PMID: 387404; and Visfeldt J, Andersson M. Pathoanatomical aspects of malignant haematological disorders among Danish patients exposed to thorium dioxide. *APMIS.* 1995 Jan;103(1):29-36. PubMed PMID: 7695889).

118. Prospective epidemiological studies conducted on subjects who received thorotrust sustained exposures from thorium decay and its daughter products of radon-220 and radium-224 demonstrated a relatively large association between exposure to those radionuclides and non-Hodgkins Lymphoma. (ECF No. 52-1, Dr. Howard Hu Expert Report for Anthony Hines (04/01/19), Pg. 9) (citing van Kaick G, Dalheimer A, Hornik S, Kaul A, Liebermann D, Lührs H, Spiethoff A, Wegener K, Wesch H. The german thorotrust study: recent results and assessment of risks. *Radiat Res.* 1999 Dec;152(6 Suppl):S64-71. PubMed PMID: 10564940).

119. A prospective investigation of a cohort of 662 uranium mill workers which found a significantly increased incidence of lymphoma, and in which, having conducted autopsies as well, the authors demonstrated that the radioactivity in the tracheobronchial lymph nodes of the workers was primarily the result of alpha emissions from thorium-230. ATSDR. (ECF No. 52-1, Dr. Howard Hu Expert Report for Anthony Hines (04/01/19), Pg. 9) (citing Toxicological Profile

for Thorium. Agency for Toxic Substances and Disease Registry in collaboration with the U.S. Environmental Protection Agency. October 1990).

**EMERY WALICK, III**

**Emery Walick's Exposure to Radionuclides**

120. Mr. Walick was a resident of St. Louis, Missouri from birth (1990) to age 8 (1998). (Ex. L, Emery Walick Plaintiff Questionnaire, Pg. 2, 3 and Attachment to Pg. 3).

121. Mr. Walick resided at 11801 Larimore Road, which is located in the Spanish Lakes neighborhood in the 63138 zip code. *Id.*

122. His family residence at 11801 Larimore Road is approximately 8.0 miles northeast of the Hazelwood Interim Storage Site (HISS)/Futura Site, 2.6 miles southeast of Coldwater Creek, and 7.75 miles north, northeast of the Saint Louis Airport Site (SLAPS). *Id.*

123. As a child, Mr. Walick would spend most days playing along the Coldwater Creek basin, in particular, in the area of his cousin's home on Wente Place (located in the 63042 zip code) 2.25 miles northwest Coldwater Creek near Pershall Road. *Id.* at p. 9 and Attachment, Ex. L.

124. Emery and his cousins played in Coldwater Creek, fished in Coldwater Creek, caught crawdads from Coldwater Creek, rode their bikes in and around the Creek, from the time he was 4 years old through high school (2008). *Id.* at Pg. 9 and Attachment; Ex. M, Deposition of Emery Walick , Pg. 38:6-12; 45:18-46:3; 56:16-22).

125. Mr. Walick testified that at his cousin's home on Wente Place, he would frequently play on the trails along Coldwater Creek and swim there. (Ex. M, Deposition of Emery Walick , Pg. 38:6-12; 45:18-46:3).

**Mr. Walick's Diagnosis of Brain Cancer**

126. In April of 2014 a brain CT scan revealed a 4 cm hypodensity in Mr. Walick's right inferior cerebellum, with mild ventriculomegaly. (ECF 52-2, Dr. Howard Hu Expert Report for Emery Walick, III (04/01/19), Pg. 3).

127. Two days after this brain scan, Mr. Walick underwent neurosurgery, during which a small blue cell tumor was removed with a pathology consistent with a medulloblastoma. (ECF 52-2, Dr. Howard Hu Expert Report for Emery Walick, III (04/01/19), Pg. 3).

**Dr. Hu's Expert Opinion ruled out other causes of Mr. Walick's Brain Cancer**

128. Dr. Hu ruled-out that Mr. Walick's Brain Cancer was caused by alternative causes other than Defendants' radioactive waste, and the Court did not exclude these opinions, finding them sufficiently reliable to be admissible. Mem. and Ord. pp. 39-40; Hu. Walick Report, pp. 12-13, ECF No. 52-2; Hu Supplemental Walick Report, pp. 2-4, ECF No. 52-17.

**Dr. Hu's General Causation Opinions Regarding Defendants' Radioactive Waste and Mr. Walick's Brain Cancer.**

129. Dr. Hu notes that the International Agency for Research on Cancer (IARC) designated ionizing radiation (in the form of X radiation or gamma radiation) as a known risk factor for the development of brain cancer based on sufficient evidence in humans. (ECF 52-2, Dr. Howard Hu Expert Report for Emery Walick, III (04/01/19), Pg. 9).

130. Dr. Hu opines that thorium exposure is capable of causing brain cancer as thorium sheds carcinogenic alpha-particles, and based on autopsy studies, thorium deposits in the brain. (ECF 52-2 Dr. Howard Hu Expert Report for Emery Walick, III (04/01/19), Pg. 9).

131. Dr. Hu opines that there is a strong association with exposure to thorium, radon-220 and radium 224 exposure and brain cancer. (ECF 52-2, Dr. Howard Hu Expert Report for Emery Walick, III (04/01/19), Pg. 9-10).

132. Dr. Hu notes that Mr. Walick's exposures occurred during childhood (birth to 18 years of age), which he opines is known to be an age at which individuals are more susceptible to carcinogenic exposures. (ECF 52-2, Dr. Howard Hu Expert Report for Emery Walick, III (04/01/19), Pg. 11).

133. Dr. Hu notes in his report that according to the ATSDR's draft Report, testing demonstrated that Thorium-230 was present in soil and sediment at levels consistently above typical background levels (1-3 pCi/g). (ECF 52-2, Dr. Howard Hu Expert Report for Emery Walick, III (04/01/19), Pg. 5).

134. Dr. Hu also notes that according to the ATSDR's Draft Report, Thorium-230 was also detected frequently above FUSRAP's remedial goal for contamination in soil (14-15 pCi/g). (ECF 52-2, Dr. Howard Hu Expert Report for Emery Walick, III (04/01/19), Pg. 5).

135. Dr. Hu notes in his report that the specific radionuclides associated with Coldwater Creek (Uranium-238, Uranium-236, Thorium-230, Thorium-232, and Radium-226), the associated ionizing radiation (which raises the risk of cancer, as noted above) generally takes the form of alpha particles, beta particles, and, to some extent, gamma radiation, which are released during the decay process and that each one is carcinogenic (able to cause cancer). (ECF 52-2, Dr. Howard Hu Expert Report for Emery Walick, III (04/01/19), Pg. 7).

136. The International Agency for Research on Cancer considers all internalized radionuclides that emit either alpha particles or beta particles to be carcinogenic to humans. (ECF 52-2, Dr. Howard Hu Expert Report for Emery Walick, III (04/01/19), Pg. 7-8).

137. The 2018 ATSDR draft report determined that many residents were likely subject to radionuclide exposures to some degree through inhalation, ingestion and skin contact and that the magnitude of the doses received, particularly in the past, likely exceeded background levels to

a significant degree for some residents. (ECF 52-2, Dr. Howard Hu Expert Report for Emery Walick, III (04/01/19), Pg. 8).

138. In its 2019 report, the ATSDR stated that, “most regulatory and advisory agencies assume every dose of radiation, no matter how small, incrementally increase the risk of developing cancer.” ATSDR Public Health Assessment for Evaluation of Community Exposures Related to Coldwater Creek (2019), Pg. 21, ECF No. 50-3.

### **KENNETH KOTERBA**

#### **Kenneth Koterba’s Exposure to Radionuclides**

139. Mr. Koterba has been a resident of St. Louis, Missouri from age 3 (1960) through 1975 and again from 1978 through the present day. (Ex. N, Emery Walick Plaintiff Questionnaire, Pg. 2, 3 and Attachment to Pg. 3).

140. Mr. Koterba resided primarily at 1303 Criterion Avenue, which is located in the Spanish Lakes neighborhood in the 63138 zip code. *Id.*

141. His family residence at 1303 Criterion Avenue is approximately 7.8 miles northeast of the Hazelwood Interim Storage Site (HISS)/Futura Site, 1.9 miles southeast of the exit of Coldwater Creek, and 8.5 miles north, northeast of the Saint Louis Airport Site (SLAPS). *Id.*

142. According to Mr. Koterba, as a child he would spend most days playing along the Coldwater Creek basin, in particular, in the area of his Uncle’s home at 285 Moule Drive (located in the 63031 zip code) 3.25 miles north of the HISS/Futura Site and north of the SLAPS site. *Id.*; ECF No. 52-13, Deposition of Kenneth Koterba, Pg. 64:21-65:2).

143. Ken and his friends played in Coldwater Creek, fished in Coldwater Creek, caught crawdads from Coldwater Creek, rode their bikes in and around the Creek, and later Ken would search the banks and creek with a metal detector looking for valuables. (ECF No. 52-13, Deposition of Kenneth Koterba, Pg. 67:10-21; 59:2-63:11).

144. Mr. Koterba testified that he would unintentionally consume water from Coldwater Creek while swimming. (ECF No. 52-13, Deposition of Kenneth Koterba, Pg. 67:22-68:30).

145. Ken stated that he played year-round in and on the banks of the creek, even in the winter. (ECF No. 52-13, Deposition of Kenneth Koterba, Pg. 54:2-23).

#### **Mr. Koterba's Brain Tumor Diagnosis**

146. In late 2015, Mr. Korteba underwent MRI which revealed a small lesion on his brain stem. (ECF No. 52-3, Dr. Howard Hu Expert Report for Ken Koterba (04/01/19), Pg. 3).

147. A differential diagnosis of Mr. Koterba's tumor included hemangioblastoma (noncancerous tumor), pilocytic astrocytoma (benign, slow-growing tumor), ganglioglioma (low grade rare tumor), ependymoma (slow-growing cancer). ECF No. 52-3, Dr. Howard Hu Expert Report for Ken Koterba (04/01/19), Pg. 3).

#### **Dr. Hu's Expert Opinion ruled out other causes of Mr. Koterba's Brain Tumor**

148. Dr. Hu ruled-out that Mr. Koterba's Brain Tumor was caused by alternative causes other than Defendants' radioactive waste, and the Court did not exclude these opinions, finding them sufficiently reliable to be admissible. Mem. and Ord. pp. 39-40; Hu. Koterba Report, pp. 12-13, ECF No. 52-3; Hu Supplemental Koterba Report, pp. 2-4, ECF No. 52-16.

#### **Dr. Hu's General Causation Opinions as they Relate to Defendants' Radioactive Waste and Mr. Koterba's Brain Tumor.**

149. Dr. Hu opined that he relied on the 2018 ATSDR Draft Report entitled "Evaluation of Community Exposures Related to Coldwater Creek St Louis Airport/Hazelwood Interim Storage Site (HISS)/Futura Coatings NPL Site, North St Louis County, Missouri. EPA Facility ID MOD980633176 to determine Mr. Koterba's likely exposures of concern were. (ECF No. 52-3, Dr. Howard Hu Expert Report for Ken Koterba (04/01/19), Pg. 5).

150. Dr. Hu relied on the ATSDR's estimation of organ-specific doses (and associated cancer risks) from recreational and residential past exposures that are specific to the brain. (ECF No. 52-3, Dr. Howard Hu Expert Report for Ken Koterba (04/01/19), Pg. 5).

151. Dr. Hu notes that the International Agency for Research on Cancer (IARC) designated ionizing radiation (in the form of X radiation or gamma radiation) as a known risk factor for the development of brain cancer based on sufficient evidence in humans. (ECF No. 52-3, Dr. Howard Hu Expert Report for Ken Koterba (04/01/19), Pg. 9).

152. Dr. Hu opines that thorium exposure is capable of causing brain cancer as thorium sheds carcinogenic alpha-particles, and based on autopsy studies, thorium deposits in the brain. (ECF No. 52-3, Dr. Howard Hu Expert Report for Ken Koterba (04/01/19), Pg. 9).

153. Dr. Hu opines that there is a strong association with exposure to thorium, radon-220 and radium 224 exposure and brain cancer. (ECF No. 52-3, Dr. Howard Hu Expert Report for Ken Koterba (04/01/19), Pg. 9-10).

154. Dr. Hu notes that Mr. Koterba's exposures occurred during childhood (birth to 9 years of age), which he opines is known to be an age at which individuals are more susceptible to carcinogenic exposures. (ECF No. 52-3, Dr. Howard Hu Expert Report for Ken Koterba (04/01/19), Pg. 11).

155. Dr. Hu also notes Mr. Koterba's exposures continued through adulthood (12-21 years of age). (ECF No. 52-3, Dr. Howard Hu Expert Report for Ken Koterba (04/01/19), Pg. 11).

156. Dr. Hu notes in his report that according to the ATSDR's draft Report, testing demonstrated that Thorium-230 was present in soil and sediment at levels consistently above typical background levels (1-3 pCi/g). (ECF No. 52-3, Dr. Howard Hu Expert Report for Ken Koterba (04/01/19), Pg. 11).

157. Dr. Hu also notes that according to the ATSDR's Draft Report, Thorium-230 was also detected frequently above FUSRAP's remedial goal for contamination in soil (14-15 pCi/g). (ECF No. 52-3, Dr. Howard Hu Expert Report for Ken Koterba (04/01/19), Pg. 5).

158. Dr. Hu notes in his report that the specific radionuclides associated with Coldwater Creek (Uranium-238, Uranium-236, Thorium-230, Thorium-232, and Radium-226), the associated ionizing radiation (which raises the risk of cancer, as noted above) generally takes the form of alpha particles, beta particles, and, to some extent, gamma radiation, which are released during the decay process and that each one is carcinogenic (able to cause cancer). (ECF No. 52-3, Dr. Howard Hu Expert Report for Ken Koterba (04/01/19), Pg. 7).

159. The International Agency for Research on Cancer considers all internalized radionuclides that emit either alpha particles or beta particles to be carcinogenic to humans. (ECF No. 52-3, Dr. Howard Hu Expert Report for Ken Koterba (04/01/19), Pg. 7-8).

160. The 2018 ATSDR draft report determined that many residents were likely subject to radionuclide exposures to some degree through inhalation, ingestion and skin contact and that the magnitude of the doses received, particularly in the past, likely exceeded background levels to a significant degree for some residents. (ECF No. 52-3, Dr. Howard Hu Expert Report for Emery Ken Koterba (04/01/19), Pg. 8).

161. In its 2019 report, the ATSDR stated that, "most regulatory and advisory agencies assume every dose of radiation, no matter how small, incrementally increase the risk of developing cancer." ATSDR Public Health Assessment for Evaluation of Community Exposures Related to Coldwater Creek (2019), Pg. 21, ECF No. 50-3.

## **FACTS RELATING TO Procedural History**

162. It wasn't until ten days *after* Plaintiffs filed their cases that Chief Judge Rodney Sippel entered the Administrative Order Regarding Radionuclide Exposure Claims against Mallinckrodt LLC and/or Cotter Corporation (N.S.L.) "Administrative Order," ECF No. 63–10.

163. This Administrative Order observed that hundreds of cases have been filed, and observed that "[f]ollowing protracted pretrial proceedings, the parties to those consolidated proceedings are engaged in settlement discussions through the court-appointed mediator involving the consolidated cases and certain other cases not yet filed." *Id.*, at 1.

164. Plaintiffs' were not parties to these settlement discussions, and neither were their cases, meaning that the Administrative Order singled-out these four Plaintiffs, as it applied only to "cases that have been filed or may be filed in the future that have not been part of the consolidated proceedings or part of the settlement proceedings." *Id.*

165. These four Plaintiffs remain to this day the only four plaintiffs the Administrative Order has ever applied to; no one has filed a single case that has not been part of the settlement proceedings since the Court issued its Administrative Order. *See, McClurg Order of Consolidation, November 12, 2020, McClurg* ECF No. 980, p. 1 ("Four of the cases consolidated with this Lead Case are not subject to the settlement reached in the other consolidated cases and have, accordingly, been proceeding on a different procedural track and under separate Case Management Orders.") *See generally McClurg v. Mallinckrodt, Inc., et al.*, No. 4:12-cv-00361-AGF.

166. And these four Plaintiffs will remain the only four plaintiffs to ever have been subject to the Administrative Order; on April 12, 2022, the Court held that because the hundreds of cases, other than these four, "have all been settled and dismissed ... it would no longer achieve efficiency for the Court or the parties to transfer to the Hon. Audrey G. Fleissig for consolidated pretrial proceedings personal injury cases that have been filed or may be filed in the future

pertaining to alleged exposure to ionizing radiation and/or radionuclides arising from production of uranium for the United States by Mallinckrodt.” ECF No. 111, p. 1.

167. Ten days after Plaintiffs filed their cases, on the same day the Court entered its Administrative Order this Court entered Case Management Order No. 14 for Future Consolidated Cases Filed Against Cotter Corporation (N.S.L.) and/or Mallinckrodt, LLC. (“CMO 14”). ECF No. 63–9.

168. In CMO 14, the Court announced “the Court believes that proof of causation will be a difficult burden for the Plaintiffs to meet.” ECF No. 741, p. 2.

169. Because the Court believed causation will be difficult for the Plaintiffs, CMO 14 required Plaintiffs to establish key elements of their claims early in the cases to save all parties from needless litigation: “Accordingly, the Court finds it necessary and appropriate to require future Plaintiffs to make a threshold showing on key elements of their claims at the outset of the litigation before proceeding with more detailed and expansive discovery.” *Id.*

170. The Court entered CMO 14 to discourage “wasteful pretrial activities.” *Id.*, at 1 (quoting *Sec. Nat'l Bank of Sioux City, IA v. Day*, 800 F.3d 936, 943 (8th Cir. 2015) (quoting Fed. R. Civ. P. 16(a)(2)-(3))).

171. The Court also found CMO 14 was warranted because Defendants had just reached a settlement agreement with counsel for all of the other plaintiffs, but not these four Plaintiffs: “...and in light of the respective Master Settlement Agreements entered into by counsel for Cotter Corporation and Mallinckrodt LLC Defendants and Plaintiffs after six years of litigation, the Court finds it appropriate at this time to exercise its discretion to enter this Case Management Order (‘CMO’) in order to efficiently manage any cases against Cotter and/or Mallinckrodt and future Plaintiffs who have not heretofore been parties to this consolidated litigation.” *Id.*

172. To guard against wasteful pretrial activities, and unnecessary detailed and expansive discovery, CMO 14 required Plaintiffs to produce, within 60 days of filing, complete expert reports “fully complying with Federal Rule of Civil Procedure 26(a)(2)” on ten different topics:

Cotter:

- a. the concentrations of effluent discharges at the boundary of the Latty Avenue site (also known as the Hazelwood Interim Storage Site and/or the Futura Coatings Site, located at 9200 Latty Avenue, Hazelwood, MO) allegedly attributable to Cotter’s operations and whether such concentrations exceed the effluent limitations found in 10 C.F.R. § 20.106(a), Appendix B;
- b. the organ dose attributable to Cotter’s operations at the Latty Avenue site from 1970-1974 that each plaintiff received at each location of alleged exposure for each illness or injury resulting from said organ dose;
- c. the whole-body effective committed dose (mrem/year) attributable to Cotter’s operations at the Latty Avenue site that each plaintiff received;
- d. general causation for the injury(ies) or illness(es) alleged by the plaintiff from a medical expert opining to a reasonable degree of medical or scientific certainty that the plaintiff’s exposure to radiation from the Latty Avenue site attributable to Cotter’s operations at the site from could have caused the development of the type of injury(ies) or illness(es) alleged by the plaintiff;
- e. specific causation for the injury(ies) or illness(es) alleged by the plaintiff from a medical expert opining to a reasonable degree of medical or scientific certainty that the plaintiff’s exposure to radiation from the Latty Avenue site attributable to Cotter’s operations at the site caused or contributed to the development of the injury(ies) or illness(es) alleged by the plaintiff.

Mallinckrodt:

- a. the concentrations of effluent discharges at the boundary of the SLAPS site allegedly attributable to Mallinckrodt’s operations and whether such concentrations exceed the effluent limitations found in 10 C.F.R. § 20.106(a), Appendix B;
- b. the organ dose attributable to Mallinckrodt’s alleged operations at the 21.74-acre site in the vicinity of the St. Louis Airport in north St. Louis County, Missouri (“SLAPS”) that each plaintiff received at each location of alleged exposure for each illness or injury resulting from said organ dose;
- c. the whole-body effective committed dose (mrem/year) attributable to Mallinckrodt’s alleged operations at the SLAPS site that each plaintiff received;

- d. general causation for the injury(ies) or illness(es) alleged by the plaintiff from a medical expert opining to a reasonable degree of medical or scientific certainty that the plaintiff's exposure to radiation from the SLAPS site attributable to Mallinckrodt's alleged operations at the site could have caused the development of the type of injury(ies) or illness(es) alleged by the plaintiff;
- e. specific causation for the injury(ies) or illness(es) alleged by the plaintiff from a medical expert opining to a reasonable degree of medical or scientific certainty that the plaintiff's exposure to radiation from the SLAPS site attributable to Mallinckrodt's operations at the site caused or contributed to the development of the injury(ies) or illness(es) alleged by the plaintiff.

*Id.*, pp. 9-10.

173. To protect against wasteful pretrial activities, and unnecessary detailed and expansive discovery, the Court required Plaintiffs to produce these expert reports, within 60 days of filing, “for all known expert witnesses who will be providing such testimony.” *Id.*, at 11.

174. To protect against wasteful pretrial activities, and unnecessary detailed and expansive discovery, the Court required Defendants, should they believe Plaintiffs’ expert reports failed to “fully comply with the requirements of this Order” to give “notice of such failure by email or fax” and then Plaintiffs “shall be provided thirty (30) additional days to cure such deficiency (“Cure Period”).” *Id.*

175. Defendants never gave these Plaintiffs notice that they believed Plaintiffs’ expert reports failed to fully comply with the Court’s Order, and, as a result, Plaintiffs never received their Cure Period. *Id.*, *See also* ECF No. 104, pp. 5-6, n.3.

176. And so, without any notice of failure to fully comply with CMO 14 from either Defendant, pretrial activities and extensive discovery continued in these four cases for another two and a half years before Defendants filed their *Daubert* Motions on August 18, 2021. ECF Nos. 47, 49, and 51.

177. Plaintiffs opposed consolidation and being subject to CMO 14 on the grounds that “Consolidation is not appropriate if it causes confusion or leads to delay, inefficiency,

inconvenience, or unfair prejudice to a party. *EEOC v. HBE Corp.*, 135 F.3d 543, 551 (8th Cir.1998).” ECF No. 747, p. 2.

178. Plaintiffs argued that being subject to CMO 14 “would unfairly prejudice Butler by allowing her only 60 days to conduct discovery and prepare and produce expert reports on both general causation and specific causation (including organ dose, whole-body dose, and off-site discharge attributable to each Defendant).” *Id.*, at 2-3.

179. Plaintiffs argued being subject to CMO 14 would deny them their “right to freely choose [their] counsel while at the same time enjoying [their] right to adequate discovery.” *Id.*, at 3.

180. Plaintiffs argued they had the right to “an adequate opportunity for discovery so that she can pursue the trial strategy, including choice of counsel and experts, of her choice.” *Id.*, p. 4.

181. The Court was “not persuaded by Plaintiffs' arguments against consolidation.” ECF No. 15, p. 2.

182. The Court determined that consolidating these cases and subjecting Plaintiffs to CMO 14 “reduces the burden on the parties. Moreover, consolidation may permit these Plaintiffs to take advantage of the discovery produced by Defendants over the past six years of litigation of the Lead Case.” *Id.*

183. It did not permit the Plaintiffs to take advantage of the expert analysis of that discovery; Dr. Clark confirmed in his deposition “that a settlement had been reached which prevented the experts from being able to use the data that -- or use the analysis that they had previously performed.” ECF 50-2, at 48:18-22.

184. The analysis that the settlement denied Dr. Clark access to “took multiple years.” ECF 50-2, 47:5-6.

185. Access to this analysis, or multiple years to re-create it, would assist in an alternative to using the ATSDR’s method to calculate each Plaintiffs’ doses, which would utilize what is known as a source term analysis. ECF 50-2, 44:16-49:21.

186. Defendants’ experts define source term analysis as “the characterization and quantification of the material released to the environment,” and describe it as a “key step” in the dose reconstruction process. (Ex. O, 2-2 and 2-3).

187. Here, the other plaintiffs’ experts were afforded the time to perform a source term analysis which “took multiple years.” ECF 50-2, 47:5-6.

188. And Defendants’ experts were afforded the time to review and rely on almost One Hundred Thousand (100,000) pages of documents before producing their reports in *McClurg*. *McClurg*, ECF No. 711-6, p. 97.

189. Dr. Clark was denied access to this source term analysis in order to perform the dose reconstruction this Court required him to do within 60 days. ECF 50-2, 44:16-49:21.

190. In fact, contrary to being to take advantage of the years of discovery, because Dr. Clark was retained by different counsel, he was told by “Tor Hoerman and the Environmental Law Group” that he “could not use that data -- and those analyses.” Ex. B, 48:11-15.

191. He was told “that a settlement had been reached which prevented the experts from being able to use the data that -- or use the analysis that they had previously performed.” *Id.*, at 48:18-22.

192. As such, his only option was to utilize the ATSDR’s method, tailoring it to the years and exposure for each Plaintiff:

So I had to -- because I was enjoined from using any of that data, I had to use a 8 different approach. And that approach that I determined was the most appropriate was to rely on the method that ATSDR, a party that's not involved in this litigation at all, had come up with to determine the dose.

So since I was enjoined from using any of that, I couldn't go back and do the same type of analysis.

What I had to do under the time constraints, which my understanding was we had to produce -- I had to produce a report within 60 days of being hired that said, what is the dose that each of these individuals received. And the only thing that I could do within that timeframe was to produce the dose -- the -- an exposure assessment based upon publicly available data. That data, the Army Corps' data, the ATSDR methodology, which summarizes the data north of the 270, provides a reasonable estimate of a baseline exposure analysis for these folks.

The analysis could not -- because of what I was enjoined from doing, could not incorporate the additional pathways of materials migrating off of SLAPS, when it was present as a storage facility, the dispersion of particulate matter off there, and then could not incorporate the dispersion from the HISS or Latty Avenue site into the community as well.

So this exposure analysis focused solely on what was available from publicly available data.

*Id.*, 45:6-46:13.

193. In finding this method to not pass the *Daubert* standard, this Court faulted it for being “created for this litigation.” ECF No. 104, p. 35.

194. But, given the time restraints placed on him by the Court, an exposure analysis under any other methodology “just wasn’t going to happen”:

Q. Did you consider using any other type of methodology other than the ATSDR methodology for this report?

A. I considered using multiple methodologies, including RESRAD and the GENII model, which I've used previously. And I determined that for -- given the amount of time that I had to produce these reports, the ATSDR method would be the most robust for the available data that I had.

The other models would also produce reliable estimates, but this one provided me an estimate which I could then compare against an authoritative body to say, is this consistent with what they're finding.

So the approach ultimately, using RESRAD or GENII -- I determined that some of the variables that I really needed for that one, the ones that really made that analysis quite robust, were not available to me. So I was going to pare it down to the model which provided the most robust estimate with the available exposure assumptions.

Q. What input did you need for the RESRAD model to make it the most robust or more robust?

A. This is related to the dispersion model.

Q. So do you need the outputs from an AERMOD time model?

A. Correct.

Q. How about --

A. And to do that, I need the source terms ahead of time, and as I testified previously, that was something that took several years to compile and come up with an estimate. So trying to pull that together within 60 days and then run a dispersion model and then layer that in there, it just wasn't going to happen.

Clark Dep., 66:12-67:24.

195. Meanwhile, Defendants' experts were afforded enough years to study almost One Hundred Thousand (100,000) pages of documents before preparing their reports. *McClurg*, ECF No. 711-6, p. 97.

196. In fact, before Plaintiffs even filed their cases, Defendants' experts had worked for over three years on these cases, generating over 689 pages of invoices totaling over \$2.1 Million. *McClurg*, ECF No. 711-2.

Respectfully Submitted,

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**ATTORNEYS FOR PLAINTIFFS**

**CERTIFICATE OF SERVICE**

I hereby certify that on the 17<sup>th</sup> day of June, 2022, I electronically filed the above with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to counsel of record.

/s/ Jonathan Soper